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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/560,046**

Applicant(s)  
**Greenspan**

Examiner  
**John Pak**

Art Unit  
**1616**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 17, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-37 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☒ Claim(s) 21-23 is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-20, and 24-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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Claims 1-12 and 15-37 are pending in this application.

Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 18 recites at line 3, "mixing the topical antibiotic". There is no antecedent basis for "the" topical antibiotic. Dependent claim does not cure this defect.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 8, 34 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 of prior U.S. Patent No. 6,338,751. This is a double patenting rejection. Although claims 1-2 of the patented claims do not explicitly recite a carrier, a carrier or an additional substance that acts as a carrier is included there because the patented claims are recited in terms of "comprising." The same invention is being claimed herein.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 15-17, 20, 24-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent No. 5,834,008. Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill in the art would have recognized the "non-linked, small particles" language in applicant's claims is encompassed by the small particle size range (less than 2 microns, see claim 5 in the cited '008 patent). Additionally, "accelerated healing"

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feature in applicant's claims would have been obvious to the ordinary skilled artisan from the "healing of wounds and burns" claim feature in the '008 patent: healing of wound by application of an external therapeutic agent would seem to necessarily cover accelerated healing. SEM or laser light scattering techniques for measuring particle size in applicant's dependent claims are noted, but since the '008 patent already claims the same sizes as applicant's claims, such measuring techniques do not affect the composition that is being claimed. While a wound dressing is not explicitly disclosed in the '008 patent claims, the ordinary skilled artisan would have been motivated to utilize the bioactive glass in such dressing form because wounds and burns require dressings and dressings by necessity come into contact with the wounds and burns. Incorporating the bioactive glass in the dressing would therefore have been advantageous to the ordinary skilled artisan and would have been fairly suggested. Lastly, while reducing level of inflammation in a wound or reducing level of bacterial infection is explicitly disclosed in the '008 patent claims, the same effect would necessarily have been obtained due to the same bioactive glass being applied to the same substrate (and also due to additional topical antibiotics in the patent claims). Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of claims 1-9 and 12 of the patented claims.

Claims 1-12, 15-20, 24-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No.

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6,428,800. Although the conflicting claims are not identical, they are not patentably distinct from each other because “accelerated healing” feature in applicant’s claims would have been obvious to the ordinary skilled artisan from the “healing of wounds and burns” claim feature in the ’800 patent: healing of wound by application of an external therapeutic agent would seem to necessarily cover accelerated healing. SEM or laser light scattering techniques for measuring particle size in applicant’s dependent claims are noted, but since the ’800 patent already claims the same sizes as applicant’s claims, such measuring techniques do not affect the composition that is being claimed. While reducing level of inflammation in a wound or reducing level of bacterial infection is explicitly disclosed in the ’800 patent claims, the same effect would necessarily have been obtained due to the same bioactive glass being applied to the same substrate (and also due to additional topical antibiotics in the patent claims). Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of the patented claims..

Claims 1, 7-9, 32-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,171,986.

Although the conflicting claims are not identical, they are not patentably distinct from each other because “accelerated healing” feature in applicant’s claims would have been necessarily present in the bioactive glass claimed in the ’986 patent. SEM or laser light scattering techniques for measuring particle size in applicant’s dependent claims are noted, but since the ’986 patent

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already claims the sizes required in applicant's claims, such measuring techniques do not affect the composition that is being claimed. Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of the patented claims.

Claims 1-4, 7-8, 32-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,972,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because "accelerated healing" feature in applicant's claims would have been necessarily present in the bioactive glass claimed in the '384 patent. Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of the patented claims.

Claims 1, 7, 9-10, 32-33, 35-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 16 of U.S. Patent No. 5,981,412. Although the conflicting claims are not identical, they are not patentably distinct from each other because the bioactive particles claimed in the '412 patent would necessarily have the properties claimed in the instant application claims due to the fact that they are made of the same components. While it is recognized that the patented claims refer to an implant use, it is the composition per se that is being examined, not how the composition will be subsequently

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used. The composition per se in the patented claims recite bioactive glass that the instant application claims encompass. SEM or laser light scattering techniques for measuring particle size in applicant's dependent claims are noted, but since the '412 patent already claims the same sizes as applicant's claims, such measuring techniques do not affect the composition that is being claimed. Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of claims 1-2 and 16 of the patented claims.

Claims 1, 7, 9-10, 32-33, 35-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,338,751. Although the conflicting claims are not identical, they are not patentably distinct from each other because the bioactive particles claimed in the '751 patent would necessarily have the properties claimed in the instant application claims due to the fact that they are made of the same components. While it is recognized that the patented claims refer to a dental use, it is the composition per se that is being examined, not how the composition will be subsequently used. The composition per se in the patented claims recite bioactive glass that the instant application claims encompass. SEM or laser light scattering techniques for measuring particle size in applicant's dependent claims are noted, but since the '751 patent already claims the same sizes as applicant's claims, such measuring techniques do not affect the composition that is being claimed. Therefore, one of ordinary skill in the art would have recognized above noted claims of the instant application as being an obvious variant of claims 1-2 of the patented claims.



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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 7, 8, 32-34 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hench et al. (US 5,840,290).

Hench et al. explicitly disclose bioactive glass particles that are formulated with dextran as a homogenous aqueous suspension (see claims 1-3; see from column 3, line 27 to column 4, line 53). Same required components and clearly overlapping percentages are disclosed as components and percentages required in applicant's claims (compare Hench's column 3, lines 31-40 and column 4, Table 1 to applicant's claims 7-8 and 33-34). While it is recognized that the Hench's invention is directed to an injectable formulation, it is the composition per se that is being rejected here, not how the composition will be subsequently used. The composition per se taught by Hench et al. recite bioactive glass formulations that the instant application claims

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encompass, and such formulations would necessarily have the properties claimed in the instant application claims due to the fact that they are made of the same components.

The claims are thereby anticipated, or in the alternative rendered obvious within the meaning of section 103(a) because the same composition has been explicitly disclosed by Hench et al.

Claims 1, 7, 8, 32-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Low et al. (US 4,851,046).

Low et al. explicitly disclose bioactive glass particles that is formulated with physiological saline (column 5, Table 2; column 6, Table 3; column 7, lines 3-4). Same required components and same percentages are disclosed as components and percentages required in applicant's claims. While it is recognized that the Low's invention is directed to periodontal repair, it is the composition per se that is being rejected here, not how the composition will be subsequently used. The composition per se taught by Low et al. recite bioactive glass formulations that the instant application claims encompass, and such formulations would necessarily have the properties claimed in the instant application claims due to the fact that they are made of the same components.

The claims are thereby anticipated, or in the alternative rendered obvious within the meaning of section 103(a) because the same composition has been explicitly disclosed by Hench et al.

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Claims 21-23 are allowed. A search update will have to be performed during the preparation of the next Office Action. If applicant is in knowledge of any patents that may issue subsequent to this Office action, which patents raise an issue double patenting with respect to claims 21-23, early filing of terminal disclaimer(s) is suggested to expedite prosecution.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Friday from 7:30 AM to 4 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600